

## REMARKS/ARGUMENTS

The rejections presented in the Office Action dated November 2, 2005 (hereinafter Office Action) have been considered. Claims 1-66 remain pending in the application. Applicant appreciates the Examiner's conscientious review and consideration of Applicant's remarks presented in the previous responsive communication.

Independent claims 1, 18, 33, 48, and 55 have been amended. No claims have been added or canceled. Reconsideration of the pending claims as amended and allowance of the application in view of the present response is respectfully requested.

Claims 1, 2, 6-9, 27-28, 33-42, 48 and 49 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,628,730 to *Shapland et al.* (hereinafter "*Shapland*"). For the following reasons, Applicant respectfully asserts that these claims are not anticipated by *Shapland*. Applicant notes that claims 27 and 28 depend from claim 18, which is not listed in the Office Action as being rejected under 35 U.S.C. §102(b) as being anticipated by *Shapland*. Applicant's discussion below is equally applicable to such a rejection of base claim 18.

*Shapland* discloses a phoretic balloon catheter for delivering a drug or combination of drugs. The disclosed balloon catheter is configured for use in a body passageway such as a blood vessel, urinary tract, intestinal tract, kidney ducts or wind pipe.

*Shapland* does not disclose nor contemplate an implantable cardiac lead. One skilled in the art would not consider the drug delivering balloon catheter of *Shapland* to be a cardiac lead, such as one capable of sensing cardiac activity and/or stimulating cardiac tissue.

Moreover, *Shapland* fails to disclose or suggest a cardiac electrode supported by a lead body. The electrode 28 within catheter body 11 shown in Figure 6 of *Shapland* is described as one of two electrodes that is used to implement the iontophoretic process of Figure 6. Nowhere in *Shapland* is there a teaching that electrode 28 is capable of use as both a iontophoretic electrode and a cardiac electrode.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Applicant respectfully asserts that *Shapland* does not provide an enabling disclosure of Applicant's claimed subject matter. *Shapland's* description of a balloon catheter having an iontophoretic electrode is insufficient to support the Examiner's anticipation rejection of Applicant's claims 1, 2, 6-9, 27-28, 33-42, 48 and 49. It is unclear how one skilled in the art could arrive at Applicant's claimed subject matter using *Shapland's* balloon catheter with iontophoretic electrode teachings without undue experimentation. The mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). *See, also*, MPEP § 2121.01.

Applicant respectfully submits that *Shapland* does not teach every element of claims 1, 2, 6-9, 27-28, 33-42, 48 and 49, and therefore fails to anticipate these claims. Clearly, *Shapland* fails to show the identical invention in as complete detail as is contained in claims 1, 2, 6-9, 27-28, 33-42, 48 and 49. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Dependent claims 2, 6-9, 27-28, 34-42, and 49, which are dependent from independent claims 1, 18, 33, and 48 respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Shapland*. While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, 33, and 48. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2, 6-9, 27-28, 34-42, and 49 are also not anticipated by *Shapland*.

Claims 4-5, 10-17, 25-26, 29-32, 44-47, 50-54 and 63-66 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Shapland* in view of U.S. Patent No. 6,416,510 to *Altman et al.* (hereinafter “*Altman*”). Claim 3 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Shapland* in view U.S. Patent No. 6,144,879 to *Gray* (hereinafter “*Gray*”). Claim 43 stands rejected under 35 U.S.C. §103(a) as being unpatentable over *Shapland* in view U.S. Patent No. 4,506,680 to *Stokes* (hereinafter “*Stokes*”).

Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142. Applicant respectfully traverses the obviousness rejection since the prior art fails to disclose all the claim limitations and there would be no motivation to combine the references as proposed by the Examiner.

*Altman* teaches an electrode having a helical coil or other fixation and penetrating element that engages and penetrates the myocardium. The myocardium is cardiac tissue residing within the heart. The *Altman* electrode is configured specifically for placement within the thoracic cavity. Hence, *Altman* clearly fails to teach an electrode configured for placement in subcutaneous non-intrathoracic tissue.

*Shapland*, as discussed above, does not teach or contemplate a cardiac electrode of any kind. The combination of *Shapland* and *Altman* fails to teach or suggest a cardiac electrode configured for subcutaneous, non-intrathoracic placement within a patient. For this reason alone, claims 4-5, 10-17, 25-26, 29-32, 44-47, 50-54 and 63-66 are patentable over the combination of *Shapland* and *Altman*.

Further, Applicant respectfully submits that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference in the manner suggest by the Examiner.

*Altman* teaches catheter delivery of drugs to myocardial tissue inside the heart. *Altman* does not teach phoresis delivery of drugs to subcutaneous non-intrathoracic tissue.

*Shapland* discloses a phoretic balloon catheter for delivering a drug(s), such as by use of iontophoresis, to body passageway such as a blood vessel, urinary tract, intestinal tract, kidney ducts or wind pipe. *Shapland* does not teach a catheter having a cardiac electrode or phoresis delivery of drugs to subcutaneous non-intrathoracic tissue.

First, there is no suggestion or motivation in *Altman* to modify *Shapland's* balloon catheter to incorporate a cardiac electrode, as *Shapland* is unconcerned about sensing or stimulating the heart.

Second, *Shapland* discloses two drug delivery implementations for use with its balloon catheter. Both are directed to transporting a drug across a drug transport wall (i.e., balloon wall) of the device. *Altman's* drug transport catheter represents a very different structure, and would appear unusable in the context of the *Shapland* device.

Applicant respectfully asserts that the teachings of *Shapland* and *Altman* would not provide sufficient guidance for one of ordinary skill in the art having these references before him/her to make the combination or modification suggested by the Examiner. Applicant respectfully asserts that the Examiner's conclusion of obviousness is, instead, based on improper hindsight reasoning using knowledge gleaned only from Applicant's disclosure.

Moreover, it appears that modifying *Shapland* using the teachings of *Altman* in the manner suggested by the Examiner is tantamount to mixing teachings out of context. Such a rejection is not permissible under § 103. See *In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000) (proposed modification must not be made in the abstract but rather made in view of the entire teaching of the prior art).

Further, the modification of *Shapland* using *Altman* would change the principle of operation of *Shapland*. As discussed above, incorporating the helical cardiac electrode into the *Shapland* device would import a cardiac sensing and/or stimulation capability not contemplated in *Shapland*. Moreover, it is not clear that *Altman's* cardiac electrode can operate as a iontophoretic electrode. Lastly, the *Altman* drug delivery approach would

appear to be unnecessary (redundant) and/or incompatible with the approaches of the *Shapland* device, as discussed above.

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

Applicant respectfully submits that claims 4-5, 10-17, 25-26, 29-32, 44-47, 50-54 and 63-66 are not rendered obvious by the combination of *Shapland* and *Altman*.

Dependent claims 4-5, 10-17, 25-26, 29-32, 44-47, 50-54, and 63-66, which are dependent from independent claims 1, 18, 33, 48, and 55, were also rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of *Shapland* and *Altman*. While Applicant does not acquiesce with any particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 18, 33, 48, and 55. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." M.P.E.P. §2143.03; *citing In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 4-5, 10-17, 25-26, 29-32, 44-47, 50-54, and 63-66 are also allowable over the combination of *Shapland* and *Altman*.

Concerning the rejection of independent claims 18 and 55 on page 5 of the Office Action, the Examiner contends that *Altman* is considered to disclose the claimed invention discussed previously in the Office Action and further including a can coupled to the lead, where the can is configured to provide phoresis delivery of a pharmacological agent from at

least a portion of the can to subcutaneous tissue. Specific reference is made by the Examiner to column 19, lines 1-15 of *Altman*. The Examiner then contends that it would have been obvious to combine the teachings of *Shapland* with *Altman* for the purpose of holding pharmacological agents for subsequent distribution.

Respectfully, the above characterization of *Altman* is in error. First, *Altman* fails to disclose a cardiac electrode configured for subcutaneous, non-intrathoracic placement within the patient. As previously argued, one skilled in the art would not consider the endocardial helical electrode of *Altman* to be a cardiac electrode configured for subcutaneous, non-intrathoracic placement.

Second, Applicant is unable to locate a description of a can in *Altman*, where such a can houses power and circuitry elements of the implantable system. The portion of *Altman* relied on by the Examiner (i.e., column 19, lines 1-15) discuss an external controller and power source connected to the catheter. Moreover, nowhere in *Altman* is the term phoresis found or contemplated.

Applicant respectfully submits that independent claims 18 and 55, and their dependent claims, are patentable over the combination of *Altman* and *Shapland*, as the asserted combination fails to teach or suggest several features of these claims, and no motivation can be found to support their being combined in the manner suggested by the Examiner.

Claims 59-62 stand rejected under 35 U.S.C. §103(a) as being unpatentable over *Shapland* in view of *Altman*, and further in view of U.S. Patent No. 5,749,909 to *Schroeppel et al.* (hereinafter “*Schroeppel*”).

Claims 59-62 are dependent claims that include all of the limitations of base claim 55 and any intervening claims, and recite additional features which further distinguish these claims from the cited references. “If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.” M.P.E.P. §2143.03; citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 59-62 are also allowable over the combination of *Shapland*, *Altman*, and *Schroeppel*.

It is to be understood that Applicant does not acquiesce to Examiner's characterization of the asserted art or Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to Applicant's claimed subject matter. Moreover, Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, alternative equivalent arrangements, common knowledge at the time of Applicant's invention, officially noticed facts, and the like. Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in Applicant's pending claims and lack of motivation to combine reference teachings. Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in future prosecution.

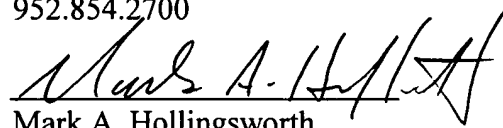
Applicant notes that the amendments to independent claims 1, 48, and 55 have been made to make explicit that which was inherent in the original claim language. Each of these claims recited a cardiac component (e.g., lead, can) that implicitly required the recited electrode to be a cardiac electrode. An amendment that only make express a recitation of a feature that was already inherent in the original claim is not a narrowing of the scope of the properly construed claim. *TurboCare v. General Electric Co.*, 264 F.3d 1111 (Fed. Cir. 2001); *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354 (Fed. Cir. 2001) and *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371 (Fed. Cir. 2001).

Authorization is given to charge Deposit Account No. 50-3581 (GUID.626PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact him at to discuss any issues related to this case.

Respectfully submitted,  
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